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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Hedrocel Vertebral Body Replacement System

Submitter Name And Address:	Implex Corp. 80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Marci Halevi
Phone Number:	(201) 818-1800
Fax Number:	(973) 829-0825
Date Prepared:	September 5, 2002
Device Trade Name:	ProxiLock Hip Prosthesis; size 12/36
Device Common Name:	Hip Stem
Classification Number and Name:	21CFR888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

Substantial Equivalence:

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

The ProxiLock Hip Prosthesis offers the surgeon a cementless option in reconstructing the hip joint on the femoral side. The stem is intended for use in the relatively younger, moderate and higher demand patient in hybrid or cementless hip arthroplasty. The Implex ProxiLock Hip Prosthesis is compatible with all Implex acetabular Hip components. The ProxiLock Hip Prosthesis is available in an array of sizes to fit a patient size range. The stem system is available without a distal slotted stem. The ProxiLock Stem is intended to be used as a cementless stem only, and is intended to cooperate with Implex Femoral Bearing Heads via a tapered locking mechanism between the neck of the ProxiLock Hip Prosthesis and the Modular Bearing Head. Implex Modular Bearing Heads are compatible with all Implex Femoral Stems.

510(k) Summary (Continued)

Indications for Use:

The ProxiLock Hip Prosthesis is intended for use where severe degeneration of the hip joint is necessary due to osteoarthritis, rheumatoid arthritis, trauma, revision of previously failed total hip arthroplasty or other pathology.

Device Technological Characteristics and Comparison to Predicate Device:

The device is unique in comparison to predicates only in regard to the manufacturing process used for the raw material (ASTM F136 Ti-6Al-4V), from plate to forged titanium alloy. Additionally, the predicate is available with and without a distal slot, the current device is available only without a distal slot.

Performance Data:

Mechanical testing was conducted (reference Appendix D) in a manner similar to the predicate device and passed the strength criteria. This testing showed that the change from plate to forged raw material does not adversely influence the strength, fatigue, or tolerances of the device.

Test data has been provided in the predicate submission regarding :

- Fatigue Testing
- Sterility Testing
- Package Integrity
- Masterfile Reference for HA
- HA Integrity in saline
- Dissolution Characteristics of HA Coating
- Modular Locking Head Test

Conclusion:

The Implex ProxiLock Hip Prosthesis is substantially equivalent to the following predicate devices identified in this premarket notification:

510(k) #	Product Name	Company
K935990	F-220 Femoral Press-Fit Hip Stem	Implex Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2002

Ms. Marci Halevi
Manager of Regulatory Affairs
Implex Corporation
80 Commerce Drive
Allendale, New Jersey 07401

Re: K022966
Trade/Device Name: ProxiLock Hip Prosthesis size 12/36 HA Coated Titanium
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: LWJ
Dated: September 5, 2002
Received: September 6, 2002

Dear Ms. Halevi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022966

Device Name: The ProxiLock Hip Prosthesis

Indications For Use:

Indications:
The ProxiLock Hip Prosthesis is intended for use where severe degeneration of the hip joint is necessary due to osteoarthritis, rheumatoid arthritis, trauma, revision of previously failed total hip arthroplasty or other pathology.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) Yes OR... Over-The-Counter Use No

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022966